

Obstacles to procurement of vaccines

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Disturbances on the Vaccine market

- **Denmark** out of stock BCG-vaccine, dT-vaccine, DTaP-IPV-Hib has not been available - > used heptavalent, Hep-A shortage
- **Finland** the national stockpile in use in April 2016
 - dT, dtap, DTaP-IPV, Polio IPV, MPR
 - BCG from alternative provider (non licenced)
- **Iceland** dTaP-IPV booster vaccination had to be postponed
 - Hepatitis A+B vaccines had to be used in stead of hepatitis A
- **Norway** DTaP-IPV stock out, DTaP-IPV-Hib critically low, BCG-vaccine from alternative source (non licenced), Rotavirus-vaccine delayed delivery
- **SITUATION YET DETERIORATING**

ECDC RAPID RISK ASSESSMENT

Shortage of acellular pertussis-containing vaccines and impact on immunisation programmes in the EU/EEA 8 October 2015

- Impact on primary immunisation program
 - Limited impact 7/20 countries
- Impact on booster doses
 - High to very high 6/20 countries

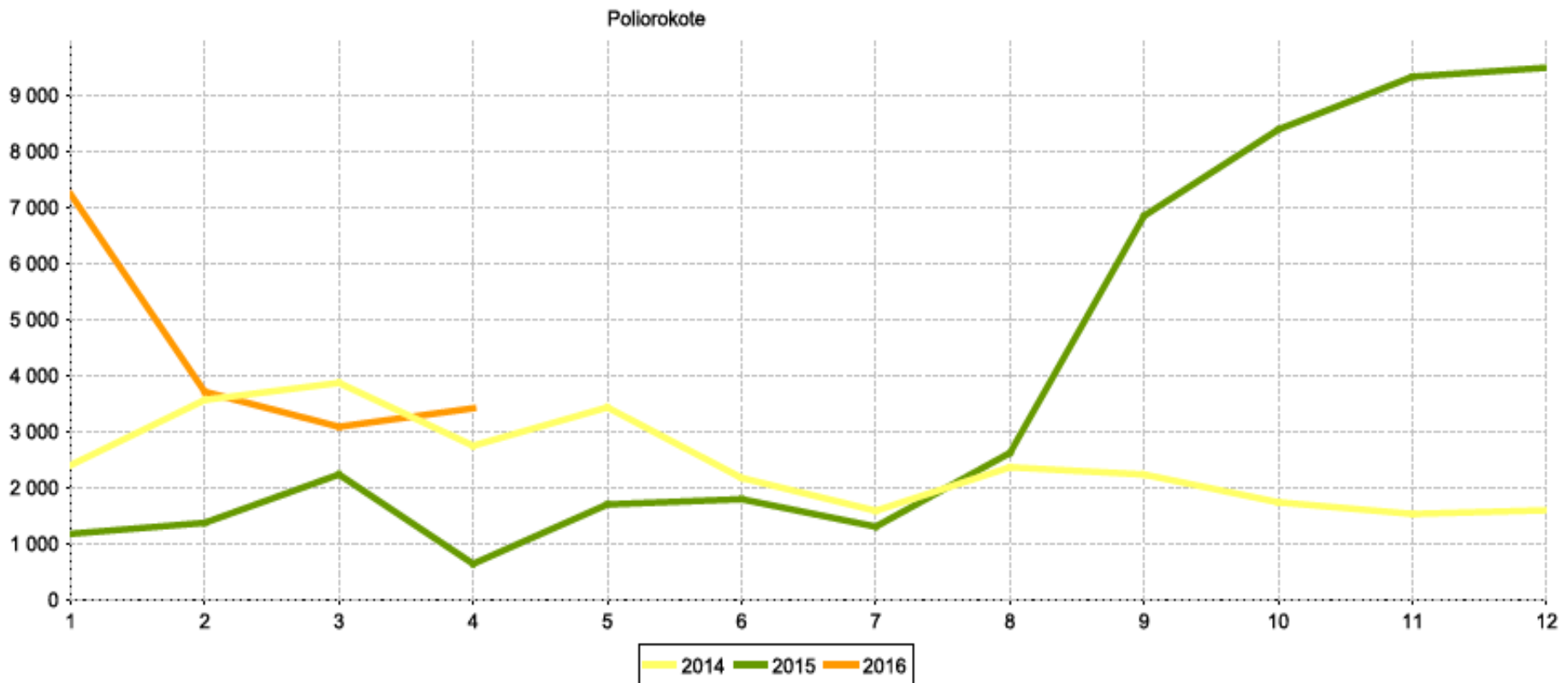
Information collection

- GlaxoSmithKline
- Pfizer
- SanofiPasteurMSD
- Statens Serum Institut (declined)

- **Buyers**
 - **Denmark, Statens Serum Institut**
 - **Iceland, Directorate of Health**
 - **Norwegian Institute of Public Health**

Thank You!

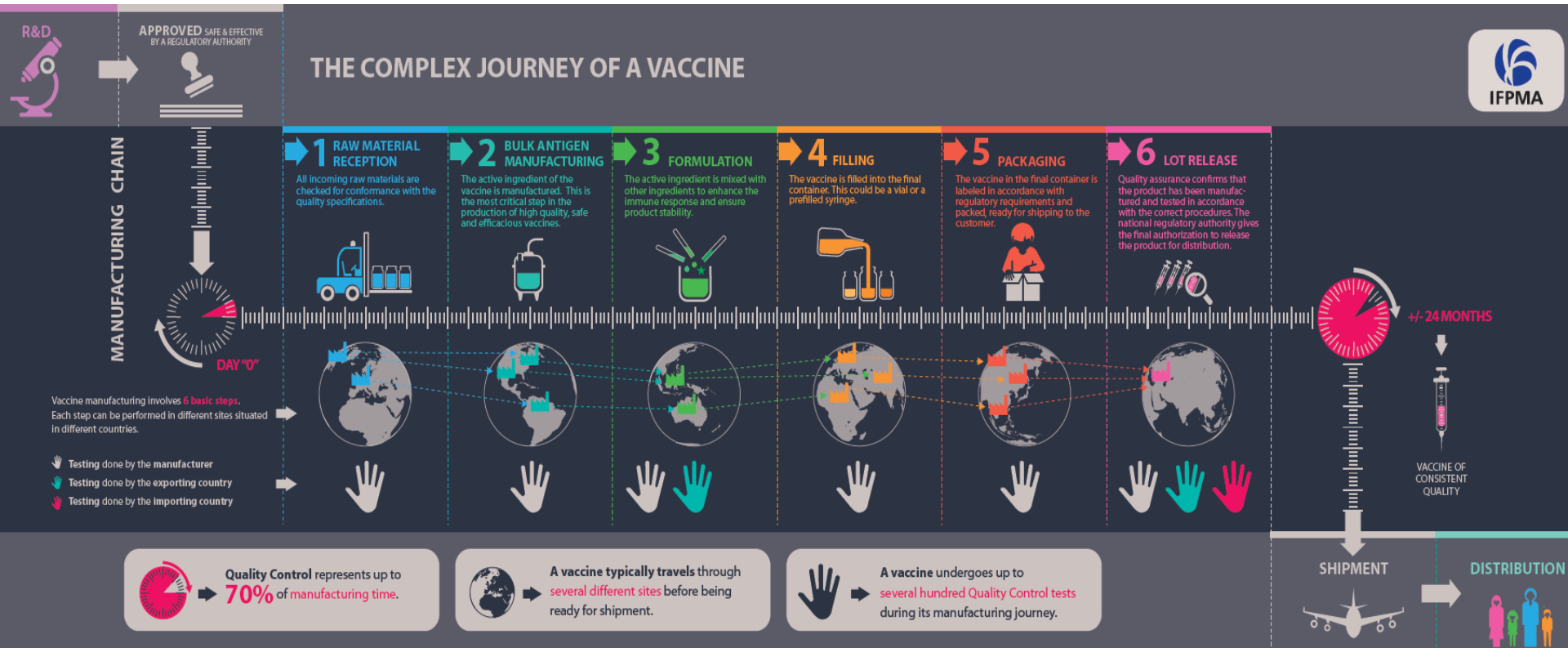
IPV consumption in Finland 2014 – 2016 impact of refugee surge



Reasons for the shortages

- Very little flexibility in production planning – it takes 18-36 months to produce a vaccine lot from planning to delivery – combination vaccines are the most time consuming
 - Unplanned demand changes take a long time to respond to
 - Increasing worldwide demand + refugee crisis
 - Only two world wide manufacturers of basic childhood vaccines left active
 - Rigid national procurement procedures
- Shortages are not related to quality issues!

Manufacturing operations to produce pediatric DTaP combination vaccines are among the most complex of the vaccine industry (slide provided by SPMSD)



http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_Complex_Journey_Vaccine_Infographic_2014.pdf

Actions taken by vaccine manufacturers

- Improved testing procedures of pertussis immunogen
 - This takes a long time to give result as it is a variation on the sales permit documentation
- Improved collection of demand signals
- Prioritize the most necessary products of the child vaccination programs
- GSK has a major project ongoing in expanding production capacity of pertussis immunogen

The manufacturers suggestions to national institutions

- An improved wide stakeholder platform of dialogue
 - Forum for early dialogue of manufacturing challenges
 - Regulatory work to reduce complexity, packaging specs
 - Work simplifying vaccination calendars across Europe
 - Flexible procurement practises
 - Early dialogue (1-2year) of upcoming tenders
- National/regional safety stock
- Contracts
 - Longer 4-7 years
 - Announcement of tenders 12-18 months in advance
 - Announcement of use of options 6-12 months in advance
 - Spacing the tenders not to coincide

Recommendations from EU institutions to vaccine supply actors

EU Commission TECHNICAL DOCUMENT
DRAFT 18.11.15

Options for dealing with vaccine shortages

- collaboration, joint procurements
- consult each other in liasion with the EU Council
- increase purchasing power
- renew tender evaluation criteria
- balance procurement risks
- review supply challenges
- dialogue with industry
- review supply challenges

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- does not give much advice to the vaccine supply actors
- build stockpiles
- obtain vaccines from non EU-countries

Thank you for your attention !

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